



CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date appearing below.

ELI LILLY AND COMPANY

By KS Rhoades

Date 6-6-05

**PATENT APPLICATION**  
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

First Applicant: James Arthur Hoffmann

Group Art Unit: 1614

Serial No.: 10/072,540

Filed: February 8, 2002

Examiner:

Delacroix-Muirheid

For: GLP-1 Formulations

Docket No.: X-11368A

**DECLARATION UNDER 37 C.F.R. 1.131**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

I, James Arthur Hoffmann, declare that:

1. I am the sole inventor and applicant in this application. I am the sole inventor of the subject matter encompassed by the claims of the above referenced patent application.
2. The experiment, events, and observations described in this declaration were performed by me and occurred in the United States.
3. I have reviewed Exhibit A submitted herewith and declare Exhibit A consists of two consecutive pages from my laboratory notebook.
4. I have reviewed Exhibit A submitted herewith and declare the subject matter described in Exhibit A falls within the pending claims of the present application. Specifically, Exhibit A records my preparation of a formulation comprising V8-GLP-1 (a GLP-1 compound), sodium phosphate tribasic (a buffer), m-cresol (a preservative) and Tween 40 or Tween 80 (polymeric surfactants) at a pH of 8.0.

5. I declare that I prepared the formulation described in Exhibit A prior to August 26, 1997.

I further declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, and that these statements are made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. 1001), and may jeopardize the validity of any patent issuing the application.

James Arthur Hoffmann  
James Arthur Hoffmann

5/10/05  
Date